K090658 MAR - 3 2010

SYNTHES®

3.0 510(k) Summary

Sponsor:
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Contact:
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Device Name: Synthes External Fixation Devices, MR Conditional

Classification: 21 CFR Part 888.3030; Single/multiple component metallic bone fixation appliances and accessories.

Predicate Devices:
Synthes Medium External Fixation
Synthes Distal Radius Fixator
Synthes Low Profile Wrist Fixator
Synthes Elbow Hinge Fixator
Synthes Large External Fixation, MR Conditional

Device Description: The Synthes External Fixation Devices, MR Conditional consists of previously cleared Medium External Fixation, Distal Radius Fixator, Low-profile Wrist Fixator and Elbow Hinge Fixator devices that are used to construct an external fixation frame.

Intended Use: Synthes External Fixation Devices, MR Conditional are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

Substantial Equivalence Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Ms. Jill R. Yelton
Manager, Regulatory Affairs
1301 Goshen Parkway
West Chester, Pennsylvania 19380

MAR - 3 2010

Re: K090658
Trade/Device Name: Synthes External Fixation Devices, MR Conditional
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance
Regulatory Class: Class II
Product Code: KTT
Dated: December 21, 2009
Received: December 22, 2009

Dear Ms. Yelton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K090658

Device Name: **Synthes External Fixation Devices, MR Conditional**

Indications for Use: Synthes External Fixation Devices, MR Conditional are intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

Synthes Medium External Fixation is intended for the construction of an external fixation frame for the treatment of pediatric and adult fractures.

Synthes Distal Radius Fixator is intended for the fixation of the distal radius.

Synthes Low-Profile Wrist Fixator is intended for stabilization of fractures of the distal radius.

Synthes Elbow Hinge Fixator is intended for supplementary treatment of complex, unstable elbow injuries when early functional stress must be limited due to persistent ligament instability. The indications for guided joint bridging with external fixators are:

- Delayed treatment of dislocated and stiff elbows
- Chronic, persistent joint instability
- Acute joint instability after complex ligament injuries
- Unstable elbow fractures
- Additional stabilization of post-operative unstable internal fixation

The Elbow Hinge Fixator is compatible with the components of the Synthes Large External Fixator System for adults (rod diameter: Ø11mm), and with components of the Synthes Medium External Fixator System (rod diameter: Ø8mm) for children and small stature adults.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090658